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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,789	03/23/2004	Geoffrey W. Hoffinan	018577-000320US	6025

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EXAMINER

LE, EMILY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,789

Applicant(s)

HOFFMAN, GEOFFREY W.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 13-18, drawn to a composition which comprises a VRSE-toxin for reducing the number of HIV infected or HIV infection susceptible cells, classified in class 424, subclass 179.1.

Group II, claim 5, drawn to an ex vivo method for reducing the number of HIV-infected cells of a host comprising exposing the HIV-infected cells or cells susceptible to HIV infection to VRSE, classified in class 424, subclass 140.1.

Group III, claims 6 and 19-21, drawn to an in vivo method for reducing the number of HIV-infected cells of a host comprising exposing the HIV-infected cells or cells susceptible to HIV infection to VRSE, classified in class 424, subclass 130.1.

Group IV, claims 9, drawn to an ex vivo method of expanding a population of T cells of a host, classified in class 424, subclass 154.1.

Group V, claims 10, drawn to an in vivo method of expanding a population of T cells of a host, classified in class 424, subclass 147.1.

Group VI, claims 19-21, drawn to a method for deleting HIV susceptible T cells in a host, classified in class 424, subclass 184.1.

Group VII, claim 22, drawn to a method for diagnosing in a subject a disease or condition or a predisposition for contacting a disease or a condition, classified in class 436, subclass 501.

Group VIII, claim 23-25, drawn to a method of treating a disease or condition in which the lymphocyte repertoire is abnormal, classified in class 435, subclass-indeterminate because of functionality defined substance.

Group IX, claims 26-28, drawn to a method for preventing a disease or condition in an individual in which lymphocyte repertoire is abnormal, classified in class 435, subclass-indeterminate because of functionality defined substance.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process of using that product, such as deleting HIV susceptible T cells and expanding T cells that are not susceptible to HIV infection.

Inventions II-V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention of Group II has separate utility such as a method of reducing the number of HIV infected cells, ex vivo; invention of Group III has separate utility such as a method of reducing the number of HIV infected cells, in vivo; invention of Group IV has separate utility such as a method of expanding a population of T cells, ex vivo; invention of Group IV has separate utility such as a method of expanding a population of T cells, in vivo. See MPEP § 806.05(d).

Inventions II-V and VI-IX are independent inventions and thus are subject to restriction. The inventions are independent processes in that the methods are not dependent on each other, not to be used together and have different functions, modes of operation or effects.

3. Claim 1, and its dependent claims 2-4 and 11, link(s) inventions II and III; and claim 7, and its dependent claims 8 and 12, link(s) inventions IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1 or 7. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

If Applicant elects Group I, Applicant is required to further specify a VRSE. Group I is directed to multiple VRSEs that are patentably distinct from the other: an antibody, and a VRSE that comprises the gp41, gp120, p24, or nef polypeptide and fragments thereof. The specification defines VRSE as an agent that binds to a T cell receptor of a V region

defined family associated with HIV infection. However, the structure encompassed by a VRSE is unknown. In the instant, the claims defines a VRSE as an antibody, or a VRSE that comprises gp41, gp120, p24, or nef polypeptide and fragments thereof. In the instant, each of the listed types of VRSE is determined to be patentably distinct from one another. A VRSE that comprises gp41, gp120, p24, or nef polypeptide and fragments thereof have chemical structures that is different from that of a VRSE that is an antibody. Thus, it is from this difference, it is rendered that each of the listed VRSEs is patentably distinct from one another. Additionally, searching all of the listed VRSEs would impose a serious search burden on the Examiner. In the instant, a different field of search would be required for each of the listed VRSE. A search for a VRSE that is an antibody would not overlap with VRSEs that comprise the gp41, gp120, p24, or nef polypeptide and fragments thereof.

If Applicant elects either Groups II-III, Applicant is required to further elect the VRSE for application in the elected method, an antibody or a VRSE-fused to a toxin. As noted above, the specification defines VRSE as an agent that binds to a T cell receptor of a V region defined family associated with HIV infection. However, the structure encompassed by a VRSE is unknown. In the instant, the claims define a VRSE as an antibody or a VRSE that is fused to a toxin. In the instant, each of the listed types of VRSE is determined to be patentably distinct from one another. A VRSE that is an antibody have a chemical structure that is different from that of a VRSE that is fused to a toxin. Thus, it is from this difference, it is rendered that each of the listed VRSEs is patentably distinct from one another. Additionally, searching all of the listed VRSEs would impose a serious search burden on the Examiner. In the instant, a different field of search would be required for

each of the listed VRSE. A search for a VRSE that is an antibody would not overlap with VRSEs that is fused with a toxin.

If Applicant elects Group VII, Applicant is required to further elect either a method for diagnosing in a subject a disease or condition OR a predisposition for contacting a disease or a condition. These two methods are patentably distinct from one another for the following reasons: each is directed to a different active method steps, and each is directed to a different population. One method is directed to the diagnosis in a subject a disease or condition, whereas the other method is directed at the diagnosis of a subject's predisposition for contacting a disease or a condition. The first method encompasses a different population than that of the second method. The diagnosis of a subject's predisposition to a condition or disease can take place prior the conception of a subject, whereas the diagnosis in a subject of a condition or disease can occur only when the subject is deemed susceptible to a certain condition or disease. Additionally, searching for both methods would impose a serious search burden on the Examiner. A search for one subject population would not encompass the other subject population.

If Applicant elects Group VIII, Applicant is required to elect the substance, an antibody or an antibody coupled to a toxin. An antibody and an antibody coupled to a toxin are patentably distinct from one another. An antibody is an immunoglobulin that is normally present in the body or produced in response to an antigen which it neutralizes; whereas an antibody toxin is a recombinant immunotoxin. Each is a patentably distinct product. A search for both of these products would impose a serious burden on the Examiner because of the different field of search that would be required. A search for an antibody would not overlap with an antibody fused to a toxin. In addition, Applicant is

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required to elect the population for treatment, autoimmune disease, cancer or allergy.

Each of these populations is patentably distinct from one another. Furthermore, a search for all populations would impose a serious burden on the Examiner because of the different field of search that would be required. A search for a cancer population would not overlap with an allergy population.

If Applicant elects Group IX, Applicant is required to elect the substance, an antibody or an antibody coupled to a toxin. An antibody and an antibody coupled to a toxin are patentably distinct from one another. An antibody is an immunoglobulin that is normally present in the body or produced in response to an antigen which it neutralizes; whereas an antibody toxin is a recombinant immunotoxin. Each is a patentably distinct product. A search for both of these products would impose a serious burden on the Examiner because of the different field of search that would be required. A search for an antibody would not overlap with an antibody fused to a toxin. Because these inventions are distinct for the reasons given above and as shown by their different classification, restriction for examination purposes as indicated is proper. Additionally, the search required for Group I is not required for any of Groups II-IX, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the

amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

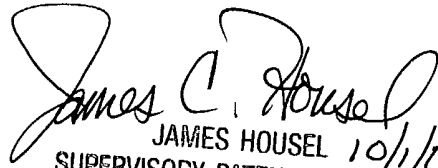
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


E.Le


JAMES HOUSEL 10/1/04
SUPERVISORY PATENT EXAMINER
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